



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

1616

RECEIVED
JAN 18 2001
TECH CENTER 1600/2900

In re the application of:

Fischetti et al.

Serial No. 09/960,472

Group: 1616

Filed: September 24, 2001

Examiner: Raj Bawa

The Honorable Commissioner of
Patents and Trademarks
Washington, D.C. 20231

PROPRIETARY INFORMATION DISCLOSURE STATEMENT

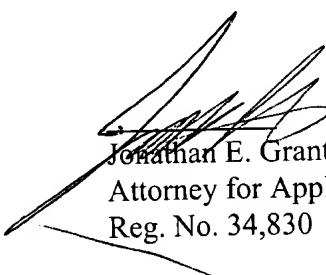
Sir:

The attached is a proprietary list of patents and patent applications filed by the inventors or the owners of the present invention. Most of the patent applications will not issue before the issue date of the above listed serial number. It is therefore requested that those patent applications on the attached list not issued prior to the issuance of the above listed patent be redacted.

Applicant provides the following summaries of the enclosed prior art, along with a Form PTO-1449, all of which are enclosed.

The statement is submitted under the provisions of 37 CFR 1.56 and 1.97(b)(1).

Respectfully submitted,


Jonathan E. Grant
Attorney for Applicant
Reg. No. 34,830

26
00000093 09960472
180.00 OP

01/16/2002 HGEBREM1 00000093 09960472

01 FC:126

180.00 OP

Jonathan E. Grant
Grant Patent Services
2120 L Street, N.W.
Suite 210
Washington, D.C. 20037
(301) 603-9071

RECEIVED

JAN 18 2001

TECH CENTER 1600/2900**Patent/Application No.****Country****Filing Date****Issue Date****Inventors****Title**

Pat. No. 5,604,109

U.S.A.

09-13-94 02-18-97

Fischetti

A Method for Exposing Group A Streptococci Antigens and an Improved Diagnostic Test for the Identification of Group Streptococcus.

Pat. No. 5,997,862
App No.09/962,523

U.S.A.

10-31-97 12-7-99

Fischetti
Loomis

Therapeutic treatment of Group A Streptococcal Infections

Pat. No. 6,017,528
App No. 09/257,025
(Cert. of Correction)

U.S.A.

02-25-99 01-25-00

Fischetti
Loomis

Therapeutic Treatment of Group A Streptococcal Infections

Pat. No. 5,985,271
No.09/257,026
(Cert. of Correction)

U.S.A.

02-25-99 11-16-99

Fischetti
Loomis

Prophylactic and Therapeutic Treatment of Group A Streptococcal Infections

Pat. No. 6,506,954
App.No. 09/395,636
(Cert. of Correction)

U.S.A.

09-14-99 05-02-00

Fischetti
Loomis

Use of Bacterial Phage Associated Lysing Enzymes for the Prophylactic and Therapeutic Treatment of Various Illnesses

Pat. No. 6,238,661
App. No. 09/497,495

U.S.A.

04-18-00 05-29-01

Fischetti
Loomis

Use of Bacterial Phage Associated Lysing Enzymes for Treating Various Illnesses

Pat. No. 6,264,945
App. No.09/482,992

U.S.A.

01-14-00 07-24-01

Fischetti
Loomis

Parenteral Use of Bacterial Phage Associated Lysing Enzymes for the Therapeutic

Treatment of Bacterial Infections

Pat. No. 6,056,955
App. No.09/395,637

U.S.A. 09-14-99 05-02-00 Fischetti Loomis

App. No. 09/654,484 U.S.A. 09-01-00 Trudil

The Use of Phage Associated Lytic Enzymes For the Rapid Detection of Bacterial Infections

App. No. 09/654,483 U.S.A. 09-01-00 Fischetti Loomis

A Composition for Treatment of A Bacterial Infection of An Upper Respiratory Tract

Pat. No. 6,254,866
App. No. 09/653,690

U.S.A. 09-01-00 07-03-01 Fischetti Loomis

Use of Phage Associated Lytic Enzymes For Treating Bacterial Infections of the Digestive Tract

App. No. 09/654,482 U.S.A. 09-01-00 Fischetti Loomis

A Composition for Treatment of a Bacterial Infection of the Digestive Tract

Pat. No. 6,277,399
App. No. 09/671,882

U.S.A. 09-28-00 08-21-01 Fischetti Loomis

Compositions Incorporating Bacterial Phage Associated Lysing Enzymes For Treating Dermatological Infections

App. No. 09/671,881 U.S.A. 09-28-00 Fischetti Loomis

A Composition for Treatment of Vaginal Bacterial Infections

.App. No. 09/671,880 U.S.A. 09-28-00 Fischetti Loomis

A Composition for Treatment of An Ocular Bacterial Infection

Pat. No. 6,248,324 U.S.A. 09-28-00 06-19-01 Fischetti

Bacterial Phage Associated Lysing

App. No. 09/671,879

Loomis
Enzymes fo Treating Dermatological
Infections

App. No. 09/671,878
U.S.A. 09-28-00

Fischetti
Loomis
The Use of Bacterial Phage Associated
Lytic Enzymes for Treating
Dermatological Infections

App. No. 09/671,991
U.S.A. 09-28-00

Fischetti
Loomis
A Composition for Treating Dental
Caries Caused by Streptococcus Mutans

Pat. No. 6,335,012
App. No. 09/671,992

U.S.A. 09-28-00 01-01-02

Fischetti
Loomis
A Method for Treating Dental Caries
Caused by Streptococcus Mutans

NOTE: THE USPTO PRINTED THE WRONG TITLE AND THE WRONG CLAIMS

Pat. No. 6,326,002
App. No. 09/671,990

U.S.A. 09-28-00 12-04-01

Fischetti
Loomis
The Use of Bacterial Phage Associated
Lysing Enzymes for Treating Bacterial
Infections of the Upper Respiratory
System

App. No. 09/704,148

U.S.A. 11-02-00

Fischetti
Loomis
Trudil
The Use of Bacterial Phage Associated
Lytic Enzymes to Prevent Food
Poisoning

App. No. 09/560,650

U.S.A. 04-28-00

Fischetti
Loomis
The Use of Bacterial Phage
Associated Lysing Enzymes for the
Prophylactic and Therapeutic
Treatment of Various Illnesses

App. No. 09/752,731

U.S.A. 01-03-01

Fischetti
Loomis
The Parental Use of Bacterial Phage
Associated Lysing Enzymes For The
Lysing Enzymes for the Therapeutic

Treatment of Bacterial Infections

Fischetti
Loomis
The Use of Bacterial Phage Associated
Lysing Enzymes for Treating Various
Illnesses

App. No. 09/932,460 U.S.A. 07-13-01

Prov. No. 60/324,089 U.S.A. 09-24-01

Fischetti
Loomis
The Use of Bacterial Shuffled and
Chimeric Phage Associated Lytic
Enzymes for the Prophylactic and
Therapeutic Treatment of
Colonization and Infections caused
By *Streptococcus Pneumoniae*

App. No. 09/960,472 U.S.A. 09-24-01

Fischetti
Loomis
The Use of Bacterial Phage
Associated Lysing Enzymes for the
Prophylactic and Therapeutic
Treatment of Colonization and
Infections Caused by *Streptococcus*
pneumoniae

App. No. 09/908,737 U.S.A. 07-19-01

Fischetti
Loomis
Parenteral Use of Bacterial Phage
Associated Lysing Enymes for the
Therapeutic Treatment of Bacterial
Infections

App. No. 09/910,940 U.S.A. 07-13-01

Fischetti
Loomis
The Use of Bacterial Phage
Associated Lytic Enzymes to
Prevent Food Poisoning

App. No. 09/844,435 U.S.A. 04-30-01

Fischetti
Loomis
The Use of Bacterial Phage
Associated Lysing Enzymes For

Treating Various Illnesses

App. No. 09/846,688 U.S.A. 05-02-01

Fischetti
Loomis

The Use of Bacterial Phage
Associated Lysing Proteins for the
Prophylactic and Therapeutic
Treatment of Various Illnesses

PCT/US99/04063 PCT 02-25-99

Fischetti
Loomis

A Means for the Prophylactic and
Therapeutic Treatment of
Streptococcal Infections

N/A	PCT	02-25-99
99909595.3	INDIA	
2000-600679	EPO	
2001126302	JAPAN	
not yet filed	RUSSIAN FEDERATION	
P19917152-0	POLAND	
514260	BRAZIL	
2001-700898	NEW ZEALAND	
200105279-4	NORTH KOREA	
N/A	SINGAPORE	
145087	CANADA	
28767/99	ISRAEL	
N/A	AUSTRALIA	
	CHINA	

Please type a plus sign (+) inside this box →

JAN 11 2002

PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet | of | 5

Complete if Known

Application Number	
Filing Date	
First Named Inventor	
Group Art Unit	1616
Examiner Name	BAWA, R.

Attorney Docket Number

U.S. PATENT DOCUMENTS

Examiner Initials'	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
		6,264,945		Fischetti et al.	07-24-2001	
		6,254,866		Fischetti et al	07-03-2001	
		6,248,324		Fischetti et al.	06-19-2001	
		6,238,661		Fischetti et al.	05-29-2001	
		6,056,955		Fischetti et al.	05-02-2000	
		6,056,954		Fischetti et al.	05-02-2000	
		6,017,528		Fischetti et al.	01-25-2000	
		5,997,862		Fischetti et al.	12-07-1999	
		5,985,271		Fischetti et al.	11-06-1999	
		5,688,501		Merril et al.	11-18-1997	
		4,957,686		Norris	09-18-1990	
		5,604,109		Fischetti et al.	02-18-1997	
		5,882,631		Suga et al.	03-16-1999	
		5,741,487		Asai et al.	04-21-1998	
		6,113,887		Mori et al.	09-05-2000	
		4,122,158		Schmitt	10-24-1978	
		3,983,209		Schmitt	09-28-1976	
		6,113,887		Mori et al.	09-05-2000	
		4,885,163		Shaar et al.	12-05-1989	

FOREIGN PATENT DOCUMENTS

Examiner Initials'	Cite No. ¹	Foreign Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Office ³	Number ⁴				
		WO 97 02351 A		CIBA GEIGY AG, et al.	01-23-1997		
		WO 96 07329 A		UNIV. MARYLAND	03-14-1996		
		EP 0 510 907 A		AGRICULTURAL & FOOD RES	10-28-1992		
		WO 99 04809 A		AMBI INC	02-04-1999		

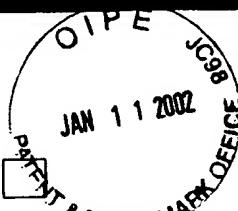
Examiner Signature

Date Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.



Please type a plus sign (+) inside this box

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

<p>Substitute for form 1449A/PTO</p> <p>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</p> <p>(use as many sheets as necessary)</p>				<p align="center">Complete if Known</p>	
Sheet	2	of	5	Application Number	
				Filing Date	
				First Named Inventor	
				Group Art Unit	1619
				Examiner Name	BAWA
				Attorney Docket Number	

U.S. PATENT DOCUMENTS

FOREIGN PATENT DOCUMENTS

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231.
DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Please type a plus sign (+) inside this box →



PTO/SB/08B (08-00)

Approved for use through 10/31/2002, OMB 0651-0031

U. S. Patent and Trademark Office: U. S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO			Complete if Known		
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>			Application Number		
Sheet	3	of	5	Filing Date	
				First Named Inventor	
				Group Art Unit	1619
				Examiner Name	BAWA
				Attorney Docket Number	

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		Reisenger, et al. (1998) "Characterization of Escherichia coli lysis using a family of chimeric E-L Genes" <i>Fems Microbiol Letter</i> . 164(1) p.159-167	
		Sheehan MM, et al. (1997) "The lytic enzyme of the Pneumococcal Phage Dp-1: a chimeric lysis of intergeneric origin." <i>Mol. Microbiol</i> . 25(4) p. 717-725	
		Young et al. (2000) "Phages will out: stragegies of host cell lysis." <i>Trends in Microbiology</i> . 8(4) p. 120-127	
		Garcia et al.(1997) "The Pneumococcal cell wall degrading enzymes: A modular design to create new lysins?" <i>Microb. Drug Resist.</i> 3(2): p. 199-211	
		Sheehan MM, et al., (1997) "The Lytic Enzyme of the Pneumococcal Phage Dp-1: a Chimeric Lysin of Intergeneric Origin" <i>Mol. Microbiol</i> . 25(4) p. 717-25	
		Garcia P, et al. (1997) "Bacteriophages of Streptococcus pneumoniae: a molecular approach" <i>Microb. Drug Resist.</i> 3(20) 165-76.	
		Sheehan, MM, et al.(1996) "Analysis of the catalytic domain of the lysis of the lactococcal bacteriophage Tuc2009 by chimeric gene assembling." <i>FEMS Microbiol.Lett.</i> 14(1): p. 23-28.	
		Sanz, JM, et al. (1996) "Construction of a multifunctional pneumococcal murein hydrolase by module assembly." <i>Eur. J. Biochem.</i> 235(3):601-5	
		Lopez R, et al. (1995) "Architecture and Domain Interchange of the Pneumococcal Cell Wall Lytic Enzymes" <i>Dev. Biol. Stand.</i> 85 p. 273-81.	

Examiner Signature	Date Considered
--------------------	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

JAN 11 2002

PTO/SB/08B (08-00)

Approved for use through 10/31/2002, OMB 0651-0031

U. S. Patent and Trademark Office: U. S. DEPARTMENT OF COMMERCE

Please type a plus sign (+) inside this box →

Substitute for form 1449B/PTO			Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>			Application Number	
Sheet	4	of	5	Filing Date
				First Named Inventor
				Group Art Unit
				Examiner Name
				Attorney Docket Number

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS

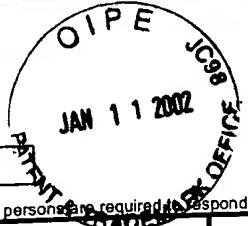
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		Croux, et al.(1993) "Interchange of Functional Domains Switches Enzymes Specificity: Construction of a chimeric pneumococcal-clostridial cell wall lytic enzyme." <i>Mol. Microbiology</i> . 9(5) p. 1019-25.	
		Diaz, E. et al. (1990) "Chimeric phage-bacterial enzymes: a clue to the modular evolution of genes. <i>PNAS</i> . 87(20) p. 8125-9.	
		Diaz, E. et al.(1990) "Chimeric pneumococcal cell wall lytic enzymes reveal important physiological and evolutionary traits." <i>J. Biol. Chem.</i> 266(9) p. 5464-71.	
		Lopez, et al. (1997) "The pneumococcal cell wall degrading enzymes: A modular design to create new lysins?" <i>Microbiological Drug Resistance</i> . 3(2) p. 199-211.	
		Loessner, et al. (1999) "Evidence for a holin-like protein gene fully embedded out of frame in the endolysin gene of <i>Staphylococcus aureus</i> Bacteriophage." (1999) <i>Journal of Bacteriology</i> . 181(15) p. 4452-4460.	
		Witte, A et al. (1998) "Characterization of Escherichia coli lysis using a family of chimeric E-L genes." <i>FEMS Microbiol. Lett.</i> , 164(1), p. 159-167	
		Martin, Ana C et al (1998): "Functional analysis of the two-gene lysis system of the pneumococcal phage Cp-1 in homologous and heterologous host cells." <i>Journal of Microbiology</i> 180(2), p. 210-217	
		Oki Masaya et al. (1997) "Functional and structural features of the holin HOL protein of the <i>Lactobacillus plantarum</i> phage phi-gle: Analysis in Escherichia coli system." <i>Gene (AMSTERDAM)</i> 197(1-2) p 137-145.	

Examiner Signature	Date Considered
--------------------	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.



Please type a plus sign (+) inside this box →

PTO/SB/08B (08-00)

Approved for use through 10/31/2002. OMB 0651-0031
U. S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Do not file if it contains a valid OMB control number.

Under the Paperwork Reduction Act of 1995, no persons are required to res

Substitute for form 1449B/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 5 of 5

Complete if Known

Substitute for form 1449B/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>		Application Number	
Sheet	5	Filing Date	
	of 5	First Named Inventor	
		Group Art Unit	1619
		Examiner Name	BAWA
		Attorney Docket Number	

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

***EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not
to be included copy of this form with next communication to applicant.

I have checked the box above if there is a check mark here if English language Translation is attached.

¹ Unique citation designation number. ² Applicant is to place a check mark here if English language translation is desired.
Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231.
DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.